

FORM PTO - 1449				ATTORNEY DOCKET NO.: EXT-048			
SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT				APPLICANT(S): Shuber			
				SERIAL NO.: 09/755,004			
				FILING DATE: January 5, 2001			
RECEIVED TECH CENTER 03 APR 29 AM 7:00 GROUP 1600/2900							
U.S. PATENT DOCUMENTS							
EXAM. INIT.		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
SPC	A25	2001/0018180	08/30/01	Shuber et al.	435	6	
	A26	2002/0004201	01/10/02	Lapidus et al.			
	A27	2002/0025525	02/28/02	Shuber			
	A28	2002/0045183	04/18/02	Shuber et al.			
	A29	2002/0048752	04/25/02	Lapidus et al.			
	A30	2002/0064787	05/30/02	Shuber et al.			
	A31	2002/0119469	08/29/02	Shuber et al.			
	A32	2002/0119472	08/29/02	Lapidus et al.			
	A33	2002/0123060	09/05/02	Boles et al.			
	A34	2002/0132251	09/19/02	Shuber			
	A35	2002/0164631	11/07/02	Shuber et al.			
	A36	2002/0172955	11/21/02	Adams et al.			
✓	A37	2003/0044780	03/06/03	Lapidus et al.	✓	✓	
OTHER ART, JOURNAL ARTICLES, ETC.							
EXAM. INIT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)						
SPC	C31	Anderson, J., "H pylori infection: Review of the guideline for diagnosis and treatment," <u>Geriatrics</u> , 55: 44-49 (Jun. 2000).					
	C32	Caselli et al., "Diagnosis of Helicobacter pylori infection by HpSA test," <u>Lancet</u> , 354(9185): 1209-1210 (Oct. 1999).					
	C33	Correa et al., "Chemoprevention of Gastric Dysplasia: Randomized Trial of Antioxidant Supplements and Anti-Helicobacter pylori Therapy," <u>J. National Cancer Institute</u> , 92(23): 1881-1888 (Dec. 2000).					
	C34	Costa et al., "Post-treatment diagnostic accuracy of a new enzyme immunoassay to detect Helicobacter pylori in stools," <u>Aliment. Pharmacol. Ther.</u> , 15: 395-401 (2001).					
✓	C35	Doig et al., "Helicobacter pylori Physiology Predicted from Genomic Comparison of Two Strains," <u>Microbiol. and Molecular Biol. Reviews</u> , 63(3): 675-707 (Sep. 1999).					
EXAMINER				DATE CONSIDERED			
Bhatia Chandra				5/5/03			

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OTHER ART, JOURNAL ARTICLES, ETC.		
EXAM. INIT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)	
<i>SPC</i>	C36	Duggan, A.E., "Testing for <i>Helicobacter pylori</i> infection: validation and diagnostic yield of a near patient test in primary care," <u>British Medical Journal</u> , 319: 1236-1239 (Nov. 1999).
	C37	Dunn <i>et al.</i> , " <i>Helicobacter pylori</i> ," <u>Clin. Microbiol. Reviews</u> , 10(4): 720-741 (Oct. 1997).
	C38	Forné <i>et al.</i> , "Accuracy of an Enzyme Immunoassay for the Detection of <i>Helicobacter pylori</i> in Stool Specimens in the Diagnosis of Infection and Posttreatment Check-Up," <u>Am. J. Gastroenter.</u> , 95(9): 2200-2205 (Sep. 2000).
	C39	Fox <i>et al.</i> , " <i>Helicobacter pylori</i> - Not a Good Bug After All," <u>N. Engl. J. Med.</u> , 345(11): 829-832 (Sep. 2001).
	C40	Gramley <i>et al.</i> , "Detection of <i>Helicobacter pylori</i> DNA in Fecal Samples from Infected Individuals," <u>J. Clin. Microbiol.</u> , 37(7): 2236-2240 (Jul. 1999).
	C41	"H. pylori Drug Resistance a Growing Problem in Germany," <u>Reuters Medical News</u> , downloaded from www.medscape.com/viewarticle/429645_print on March 13, 2002.
	C42	"H. pylori Eradication May Improve Platelet Count in Thrombocytopenia," <u>Reuters Medical News</u> , downloaded from http://gastroenterology.medscape.com/reu.../prof/2001/02/02.09/20010208clin005.htm on February 12, 2001.
	C43	" <i>Helicobacter pylori</i> and Gastric Lymphoma: A Dangerous Connection," <u>Medscape Hematology -Oncology</u> , 4(2): (2001), downloaded from http://gastroenterology.medscape.com/Medscape/oncology/journal/2001/v04.n02/ca-mo042... on April 29, 2001.
	C44	Herbrink <i>et al.</i> , "Serological Methods for Diagnosis of <i>Helicobacter pylori</i> Infection and Monitoring of Eradication Therapy," <u>Eur. J. Clin. Microbiol. Infect. Dis.</u> , 19: 164-173 (2000).
	C45	Ishihara <i>et al.</i> , "Diagnostic accuracy of a new non-invasive enzyme immunoassay for detecting <i>Helicobacter pylori</i> in stools after eradication therapy," <u>Aliment. Pharmacol. Ther.</u> , 14: 611-614 (2000).
	C46	Kerr <i>et al.</i> , "An association between sudden infant death syndrome (SIDS) and <i>Helicobacter pylori</i> infection," <u>Arch. Dis. Child.</u> , 83: 429-434 (2000).
	C47	Marais <i>et al.</i> , "Metabolism and Genetics of <i>Helicobacter pylori</i> : the Genome Era," <u>Microbiol. and Molec. Biol. Reviews</u> , 63(3): 642-674 (Sep. 1999).
	C48	Moayyedi <i>et al.</i> , "The effectiveness of omeprazole, clarithromycin and tinidazole in eradicating <i>Helicobacter pylori</i> in a community screen and treat programme," <u>Aliment. Pharmacol. Ther.</u> , 14: 719-728 (2000).
	C49	Monteiro <i>et al.</i> , "Detection of <i>Helicobacter pylori</i> DNA in human feces by PCR: DNA stability and removal of inhibitors," <u>J. Microbiol. Meth.</u> , 45: 89-94 (2001).
	C50	Monteiro <i>et al.</i> , "Magnetic Immuno-PCR Assay with Inhibitor Removal for Direct Detection of <i>Helicobacter pylori</i> in Human Feces," <u>J. Clin. Microbiol.</u> , 39(10): 3778-3780 (Oct. 2001).
EXAMINER	<i>Brabha Chunduru</i> DATE CONSIDERED 5/5/03	

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OTHER ART, JOURNAL ARTICLES, ETC.			
EXAM. INIT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)		
<i>SPC</i>	C51	Ni <i>et al.</i> , "Accurate diagnosis of <i>Helicobacter pylori</i> infection by stool antigen test and 6 other currently available tests in children," <u>J. Pediatrics</u> , <u>136</u> (6): 823-827 (Jun. 2000).	
	C52	Nilsson <i>et al.</i> , " <i>Helicobacter</i> Species Identified in Liver From Patients With Cholangiocarcinoma and Hepatocellular Carcinoma," <u>Gastroenterology</u> , <u>120</u> (1): 323-326 (Jan. 2001).	
	C53	Peña <i>et al.</i> , "Molecular Resistance Testing of <i>Helicobacter pylori</i> in Gastric Biopsies," <u>Arch. Pathol. Lab. Med.</u> , <u>125</u> : 493-497 (Apr. 2001).	
	C54	Peterson <i>et al.</i> , " <i>Helicobacter pylori</i> ," in Slesinger <i>et al.</i> , <u>Gastrointestinal and Liver Disease: Pathophysiology/Diagnosis/Management</u> , Philadelphia: W.B. Saunders, 1998: 604-615.	
	C55	Shepherd <i>et al.</i> , "Comparison of an enzyme immunoassay for the detection of <i>Helicobacter pylori</i> antigens in the faeces with the urea breath test," <u>Arch. Dis. Child.</u> , <u>83</u> : 268-270 (2000).	
	C56	Shuber <i>et al.</i> , "Accurate Non-invasive Detection of <i>H. pylori</i> DNA Before and After Treatment," oral presentation, (May 2001).	
	C57	Uemura <i>et al.</i> , " <i>Helicobacter pylori</i> infection and the Development of Gastric Cancer," <u>New England J. of Med.</u> , <u>345</u> (11): 784-789 (Sep. 2001).	
	C58	Vaira, D., "Diagnosis of <i>Helicobacter pylori</i> infection with a new non-invasive antigen-based assay," <u>Lancet</u> , <u>354</u> : 30-33 (Jul. 1999).	
	C59	Yamamoto <i>et al.</i> , "A New Rapid Test for Detecting Anti- <i>Helicobacter pylori</i> Antibody Excreted into Urine," <u>Helicobacter</u> , <u>5</u> (3): 160-164 (2000).	
<i>↓</i>	C60	Zipser <i>et al.</i> , "Is Repeat Testing Needed for <i>Helicobacter pylori</i> ?" <u>J. Am. Board of Fam. Prac.</u> , <u>13</u> (6): 449-450 (2000).	
EXAMINER	<i>Prabha Chundrase</i>		DATE CONSIDERED <i>8/5/03</i>

FORM PTO - 1449

SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT

ATTORNEY DOCKET NO.: EXT-048

APPLICANT(S): Shuber

SERIAL NO.: 09/755,004

FILING DATE: January 5, 2001

GROUP: 7637

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OTHER ART, JOURNAL ARTICLES, ETC.

EXAM. INIT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)	
88C	C15	Bélanger et al., "Rapid Detection of <i>Clostridium difficile</i> in Feces by Real-Time PCR," <u>J. Clin. Microbiol.</u> , <u>41(2)</u> : 730-734 (Feb. 2003).
	C16	Bickley et al., "Evaluation of the polymerase chain reaction for detecting the urease C gene of <i>Helicobacter pylori</i> in gastric biopsy samples and dental plaque," <u>J. Med. Microbiol.</u> , <u>39(5)</u> : 338-344 (1993).
	C17	Bravos et al., "Accurate Diagnosis of <i>Helicobacter pylori</i> ," <u>Gastroenterology Clinics of North America</u> , <u>29(4)</u> : 925-929 (Dec. 2000).
	C18	Johnston et al., "Evaluation of Three Commercial Assays for Detection of <i>Giardia</i> and <i>Cryptosporidium</i> Organisms in Fecal Specimens," <u>J. Clin. Microbiol.</u> , <u>41(2)</u> : 623-626 (Feb. 2003).
	C19	Kawamata et al., "Nested-Polymerase Chain Reaction for the Detection of <i>Helicobacter pylori</i> Infection with Novel Primers Designed by Sequence Analysis of Urease A Gene in Clinically Isolated Bacterial Strains," <u>Biochem. And Biophys. Research Comm.</u> , <u>219(1)</u> : 266-272 (Feb. 1996).
	C20	Mapstone et al., "Identification of <i>Helicobacter pylori</i> DNA in the mouths and stomachs of patients with gastritis using PCR," <u>J. Clin. Pathol.</u> , <u>46(6)</u> : 540-543 (Jun. 1993).
	C21	Monteiro, et al., "Complex Polysaccharides as PCR Inhibitors in Feces: <i>Helicobacter pylori</i> Model," <u>J. Clin. Microbiol.</u> , <u>35(4)</u> : 995-998 (Apr. 1997).
	C22	Nagashima et al., "Application of New Primer-Enzyme Combinations to Terminal Restriction Fragment Length Polymorphism Profiling of Bacterial Populations in Human Feces," <u>Applied and Environ. Microbiol.</u> , <u>69(2)</u> : 1251-1262 (Feb. 2003).
	C23	Osaki, et al., "Detection of <i>Helicobacter pylori</i> in Fecal Samples of Gnotobiotic Mice Infected with <i>H. pylori</i> by an Immunomagnetic-Bead Separation Technique," <u>J. Clin. Microbiol.</u> , <u>36(1)</u> : 321-323 (Jan. 1998).
	C24	Shuber et al., "Accurate, Noninvasive Detection of <i>Helicobacter pylori</i> DNA from Stool Samples: Potential Usefulness for Monitoring Treatment," <u>J. Clin. Microbiol.</u> , <u>40(1)</u> : 262-264 (Jan. 2002).
	C25	Song et al., " <i>Helicobacter pylori</i> in Dental Plaque: A Comparison of Different PCR Primer Sets," <u>Digestive Dis. and Sci.</u> , <u>44(3)</u> : 479-484 (Mar. 1999).
	C26	Uribe et al., "Sensitive Detection of <i>Helicobacter pylori</i> in Gastric Aspirates by Polymerase Chain Reaction," <u>The Journal of the Japanese Association for Infectious Diseases</u> , <u>72(2)</u> : 114-122 (Feb. 1998).
	C27	Watanabe, et al., "Detection of <i>Helicobacter pylori</i> Gene by Means of Immunomagnetic Separation-Based Polymerase Chain Reaction in Feces," <u>Scandinavian Journal of Gastroenterology</u> , <u>33(11)</u> : 1140-1143 (1998).
↓	C28	Weiss et al., "Comparison of PCR and Other Diagnostic Techniques for Detection of <i>Helicobacter pylori</i> Infection in Dyspeptic Patients," <u>J. Clin. Microbiol.</u> , <u>32(7)</u> : 1663-1668 (Jul. 1994).
EXAMINER	Prabha Chandra	
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EXAM. INIT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)	
SP	C29	Westblom, et al., "Diagnosis of <i>Helicobacter pylori</i> Infection by means of a Polymerase Chain Reaction Assay for Gastric Juice Aspirates," <u>Clin. Infectious Dis.</u> , <u>16(3)</u> : 367-371 (Mar. 1993).
SP	C30	Yoshida et al., "Use of a Gastric Juice-Based PCR Assay To Detect <i>Helicobacter pylori</i> Infection in Culture-Negative Patients," <u>J. Clin. Microbiol.</u> , <u>36(1)</u> : 317-320 (Jan. 1998).
EXAMINER	Brabha cheundary	DATE CONSIDERED 5/5/03

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EXAM. INIT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)		
<i>SK</i>	C13	Fermér et al., "Development and Use of a Simple Polymerase Chain Reaction Assay to Screen for <i>Helicobacter</i> spp. and <i>H. hepaticus</i> in Intestinal and Fecal Samples from Laboratory Mice," <u>Comparative Medicine</u> , 52(6):518-522 (Dec. 2002).	
<i>SK</i>	C14	Riley et al., "Identification of Murine Helicobacters by PCR and Restriction Enzyme Analyses," <u>J. Clinical Microbiology</u> , 34(4):942-946 (Apr. 1996).	
EXAMINER	<i>Bratha Chenduru</i>		DATE CONSIDERED 5/5/03

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